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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,579	10/27/2000	A. John Bramley	2001796-0006	5413

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CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/698,579	BRAMLEY ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 27-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 27-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 31, 2005 has been entered. Accordingly, claims 1-3, 27-44, and new claims 45-48 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of Claims 1-3 and 27-44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Additionally, this rejection is applied to newly added claims 45-48.

Applicants are asserting that claims 1 and 35 have been amended to now contain two specific functions that are shared by proteins encoded by the modified genes, that the protein kills Staphylococcal aureus cells by hyroloyzing pentapeptide links of the Staphylococcal cell wall. Applicants further point to the Written Description Guidelines that description of an antigen is sufficient to describe an antibody that binds to the antigen based on the functional characteristics of the antigen-antibody interaction (USPTO Written Description Guidelines, page 60). Applicants conclude that the instant

case, the claimed genes encode an active lysostaphin protein that interacts with a substrate that is specifically hydrolyzed by lysostaphin, i.e., the pentapeptide links of S. aureus cell walls. Applicants further assert that the specification either explicitly or implicitly discloses a sufficient number of species of modified genes to support a claim to a genus. Specifically, Applicants assert that "conservative substitutions are preferred since one of ordinary skill in the art will recognize that such substitutions are more likely to result in proteins that retain activity than are nonconservative substitutions.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that claims 1 and 35 have been amended to now contain two specific functions that are shared by proteins encoded by the modified genes, that the protein kills Staphylococcal aureus cells by hyroloyzing pentapeptide links of the Staphylococcal cell wall. However, the claims still provide no details as to the structure of the claimed gene. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a ***generic statement which defines a genus of nucleic acids by***

only their functional activity does not provide an adequate written description of the genus. (Emphasis added). The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Second, Applicants further point to the Written Description Guidelines that description of an antigen is sufficient to describe an antibody that binds to the antigen based on the functional characteristics of the antigen-antibody interaction (USPTO Written Description Guidelines, page 60). However, this is simply not applicable to claims directed to nucleic acids. As determined by *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a ***generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus***.

Finally, Applicants assert that the specification either explicitly or implicitly discloses a sufficient number of species of modified genes to support a claim to a genus. Specifically, Applicants assert that "conservative substitutions are preferred since one of ordinary skill in the art will recognize that such substitutions are more likely to result in proteins that retain activity than are nonconservative substitutions. However, Applicants statement simply does not meet the written description requirement. Briefly

mentioning that some amino acids can be changed anywhere within a protein, does not equate to the disclosure of multiple species which provide support for a genus claim. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016. While Applicants have described the protein identified as SEQ ID NO: 3, this species alone remains the sole example which meets the written description guidelines.

Concerning new claims 45-48. Applicants claims reciting SEQ ID NO: 3 are sufficient to meet the written description requirements. However, claims 45-48 also recite "variants" of SEQ ID NO: 3, it is the recitation of these variants, which has extended this rejection to new claims 45-48. For instance, the variant in claim 45 recites that the variant of SEQ ID NO: 3 "encodes an active lysostaphin protein in which only one of the sites for N-linked glycosylation is altered with respect to the wild type. However, this claim still encompasses structural variants which have every single amino acid altered except for one site responsible for N-linked glycosylation, the upper limit of alteration is not set forth. In other words, all amino acids from non N-linked glycosylation can be altered as set forth by the term "variant." Applicants specification, as set forth above, simply does not provide sufficient written description support for such a large genus of modified proteins. As a suggestion, amendment of the claim to recite "wherein said variant comprises SEQ ID NO: 3 and encodes an active lysostaphin protein in which the Asn in either or both of the sites for N-linked glycosylation is deleted or replaced by a different amino acid..." would be sufficient to overcome this rejection.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a modified gene alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The

court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 1-3 and 27-44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, a new matter rejection is withdrawn in view of Applicants amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
October 24, 2005